sartorius stedim biotech

User Manual

Flexsafe® 3D Bag For Drum

50L | 100L | 200L

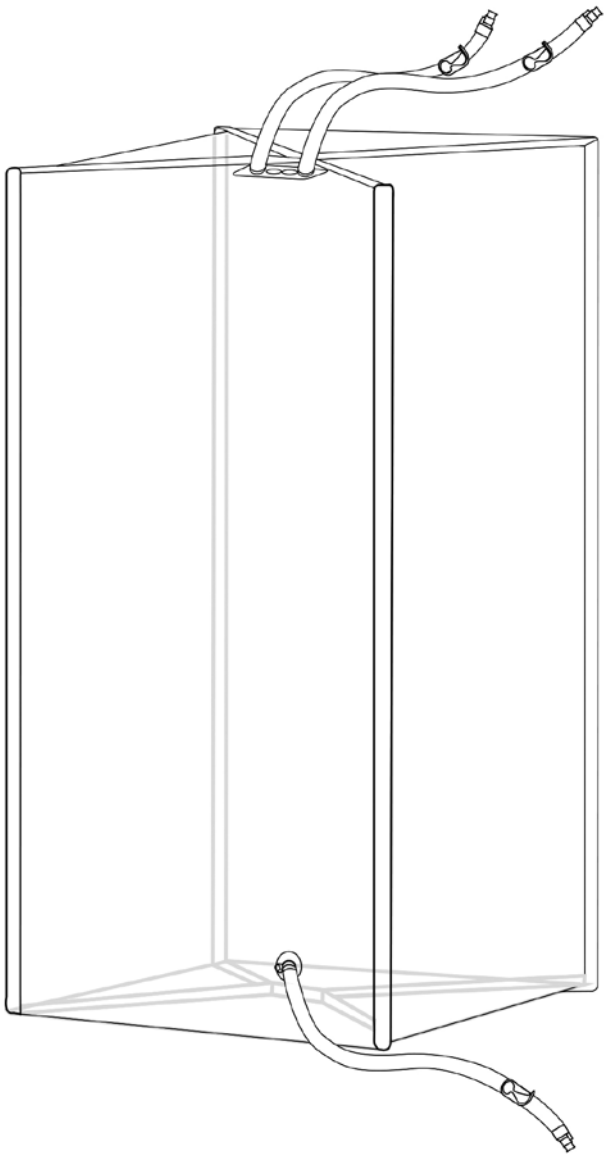

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Table of Contents

1. Introduction 4

2. Plastic Drum & Flexsafe® 3D Bag for Drum Description 5
2.1 Plastic Drum description and dimensions 5
2.2 Flexsafe® 3D Bag for Drum description 5

3. Flexsafe® 3D Bag for Drum Installation into the Drum 6

4. Flexsafe® 3D Bag Filling 8

5. Emptying Flexsafe® 3D Bags 10

6. Troubleshooting Guide 11

7. Precautions of Use 11

8. Flexsafe® 3D Bag for Drum Storage Conditions 12

9. Shelf Life of a Flexsafe® 3D Bag for Drum 12

10. Product Complaint 13

11. Disclaimers 13

12. Warranty 14

13. Trademark 14

1. Introduction

Flexsafe® 3D Bags for Drum are designed for processing and storage of large volume biopharmaceutical solutions in drum containers.

The Flexsafe® 3D Bag for Drum are available in 50L, 100L, 200L to fit plastic drums. They are available in standard either with top lines or with top and bottom lines for virtually 100% fluid recovery.

The Drum supports the fluid contained within the Flexsafe® 3D Bag. The two make up the System and must be used together to ensure a robust process solution.

The System can be moved with a dolly (up-to 200L).

Purpose
This instruction for use describes the operations required to prepare, fill and drain a 50L, 100L, 200L Flexsafe® 3D Bag for Drum in its dedicated plastic drum.

2. Plastic Drum & Flexsafe® 3D Bag for Drum Description

2.1 Plastic Drum description and dimensions

Sartorius Stedim Biotech currently offers a range of plastic drums (see Fig. 1) available in 3 sizes: 50L, 100L and 200L for use with Flexsafe® 3D Bags for Drum of the same volume.

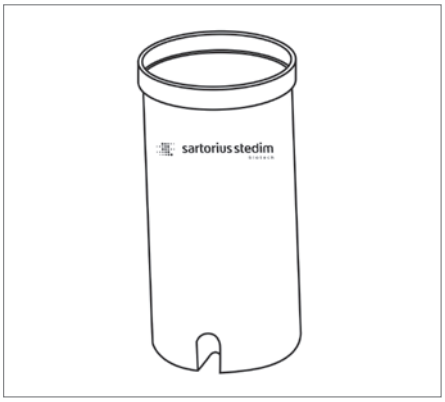


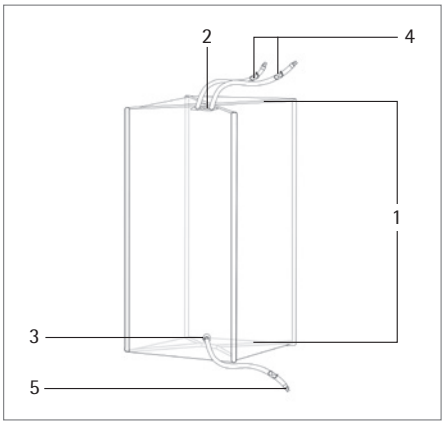
Fig. 1

Plastic drum dimensions (approx.) for Flexsafe® 3D Bag for Drum

Nominal volume in litres	Part number	Description	Drum internal diameter in mm | inches (Approx.)	Drum internal height in mm | inches (Approx.)
50L	FBC125627	STD DRUM BTM DR 50L	346 | 13 – 5/8	702 | 27 – 5/8
100L	FBC125628	STD DRUM BTM DR 100L	467 | 18 – 3/8	759 | 29 – 7/8
200L	FBC125629	STD DRUM BTM DR 200L	559 | 21 – 1/2	918 | 36 – 11/16

2.2 Flexsafe® 3D Bag for Drum description

(see Fig. 2)



1. K-seals
2. 4-port system
3. Bottom port (if applicable)
4. Filling tubes | Dispensing tubes
5. Dispensing tube (if applicable)

Fig. 2

3. Flexsafe® 3D Bag for Drum Installation into the Drum

1. Before installing the Flexsafe® 3D Bag for Drum in the plastic drum, check that the internal surfaces of the drum are smooth, dry and free of any particles that might damage the bag surface.

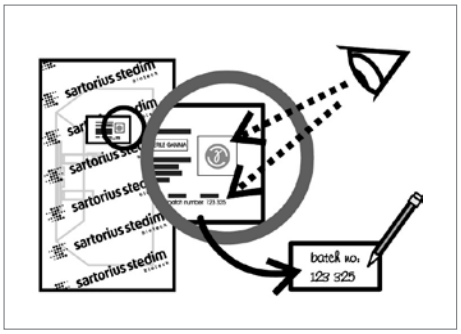


Fig. 3

2. Obtain a packaged Flexsafe® 3D Bag for Drum of the appropriate size according to your requirements. Bag sizes match drum sizes as described in the plastic drum dimensions (see 2.1. Plastic drums description and dimensions). Record the batch number of the bag (as seen on the product label). Check that the irradiation indicator on the label is red (see Fig. 3) to indicate irradiated product.

3. On a table, position the bag so that both the bottom port and the 4-port system are facing you with the bottom port underneath (if applicable) and the 4-port system uppermost. This correct positioning will ensure a proper insertion of the Flexsafe® 3D Bag in the drum.

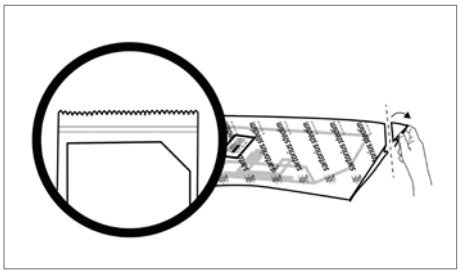


Fig. 4

4. To open and remove the secondary (external) packaging (see Fig. 4):
   – Tear open one of the corners and open completely by tearing along the weld.
   – Remove the secondary packaging by sliding it away from the Flexsafe® 3D Bag.

5. Check that the Flexsafe® 3D Bag secondary packaging is free from any damage that could compromise the sterility.

6. Repeat the 4. and 5. steps for the primary (internal) packaging.

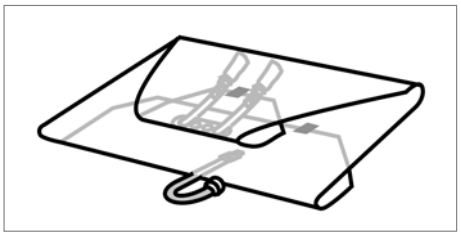


Fig. 5

7. Unfold the bag and remove any adhesive tapes or protective foams from the Flexsafe® 3D Bag (see Fig. 5).

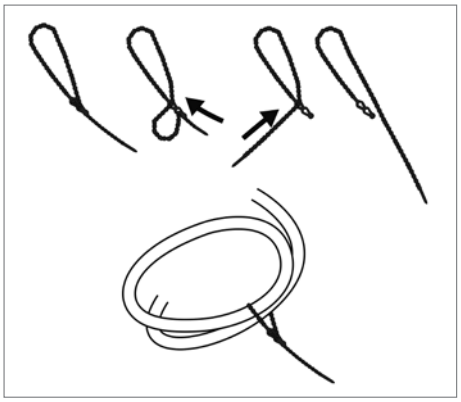


Fig. 6

8. Remove the reversible cable tie on the bottom line (see Fig. 6).

Fig. 7

9. To position the bag inside the drum (see Fig. 7):
   – Hold the folded bag on both arms with the 4-port system uppermost, facing the user and the single (bottom) port underneath (if applicable)
   – Position yourself on the side of the drum closest to the bottom hole of the drum

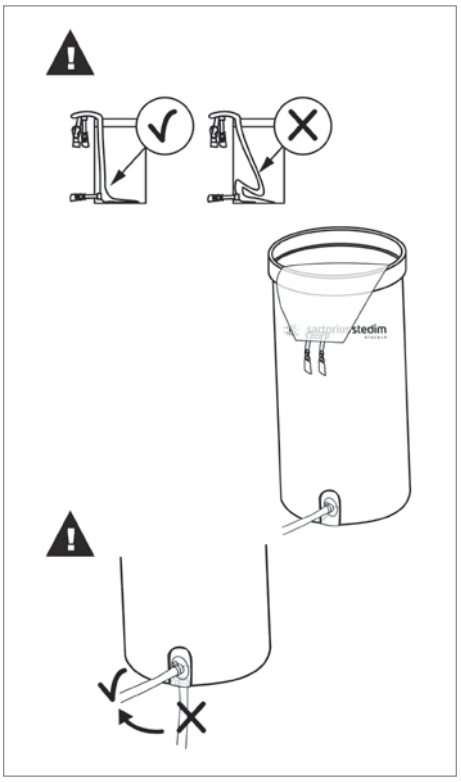


Fig. 8

10. Install the Flexsafe® 3D Bag in the drum (See Fig 8):

▷ If you are using a Flexsafe® 3D Bag with the bottom port:
   – Position the bag in such a way that the bottom port tube is positioned towards the drum bottom hole
   – Carefully feed the bottom drain line through the drum bottom hole and take it out. The bottom port must be positioned in horizontal position.
   – Unfold the bag and drape the 4-port system and the tubing onto the wall of the drum

▷ If you are using a Flexsafe® 3D Bag without the bottom port:
   – Position the bag inside the drum
   – Unfold the bag and drape the 4-port system and the tubing onto the front wall

11. Remove the reversible cable tie(s) on the top lines (see Fig. 6)

Fig. 9

12. Position all clamps as close as possible to their bag ports, remove their protection cap and close all of them (see Fig. 9).

4. Flexsafe® 3D Bag Filling

Sartorius Stedim Biotech recommends the filling through the top port of the bag.

1. Check that all clamps are closed (see Fig. 8).
2. Connect the bag to the supply line in accordance with the aseptic procedures used on your site.
3. Open any clamps on the filling line from which the bag will be filled (see Fig. 10).

Fig. 10

4. Start to fill the Flexsafe® 3D Bag – Sartorius Stedim Biotech recommends the use of peristaltic pumps for filling and dispensing from the bag.

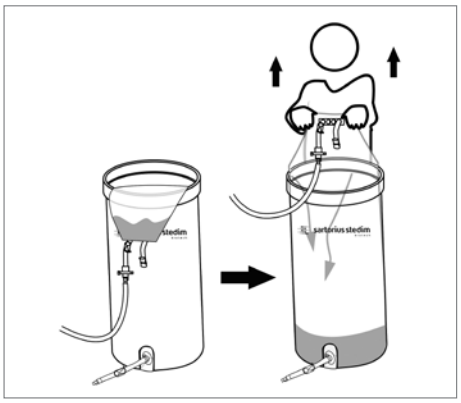


Fig. 11

CAUTION

– During filling with the first 10L of fluid, ensure the bottom port remains in horizontal position
– As the bag fills, make sure the liquid does not get trapped into the bag fold. Regularly lift the bag from the top to have the liquid falling at the bottom of the drum (See Fig. 11)

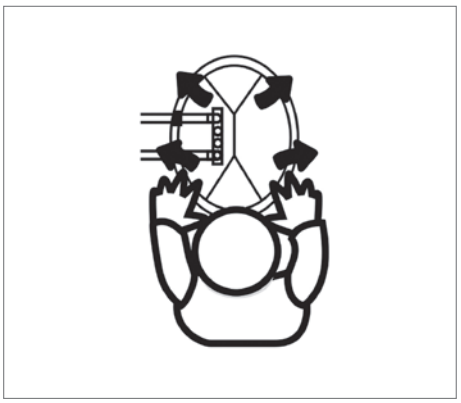


Fig. 12

5. After filling the bag to 10% of the bag's nominal capacity allowing the bottom of the bag to be completely opened out, stop filling and perform the following steps (see Fig. 12):
   – Remove the top port of the bag from the front of the drum and allow it to sit freely within the drum
   – Slightly move the Flexsafe® 3D Bag to center it in the container

6. Fill the bag to its nominal capacity and stop the filling.

Fig. 13

7. If you have chosen to fill through the top, empty the liquid contained in the filling line into the bag by raising the tube vertically over the bag (see Fig. 13).

8. Close the clamps (see Fig. 9) and disconnect the filling line.

5. Emptying Flexsafe® 3D Bags

Dispensing of the bag can be done either from the top or the bottom lines.

1. Connect the bottom tubing line to receiving system according to standard procedures for your site.

2. Open any clamps on the draining line (see Fig. 10). Drain the bag – gravity can be used using the bottom line (if applicable), but for faster draining and maximum product recovery, Sartorius Stedim Biotech recommends the use of a peristaltic pump.

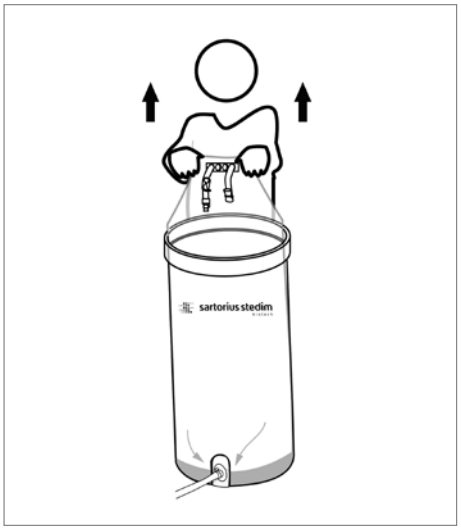


Fig. 14

3. The bag collapses as it is drained. Lift the bag at the end of the draining to obtain nearly 100% fluid recovery (see Fig. 14).

4. Once dispensing has been completed, clamp the line (see Fig. 9) and disconnect the Flexsafe® 3D Bag from the receiving system.

5. Discard the Flexsafe® 3D Bag in accordance to the procedures used on your site.

6. Troubleshooting Guide

The bag will not fill.

▷ Check that any clamps on the filling line are open and that the tubing is not pinched.

Many folds appear in the bag during filling.

▷ The bag is too big for the drum; Verify the bag size from the outer packaging and use the bag suitable for the size of the drum.

The bag does not reach the walls of the drum.

▷ The bag is too small for the drum; Verify the bag size from the outer packaging and use the bag suitable for the size of the drum.

The bag will not drain.

▷ Check that any clamps on the drain line are open and that the tubing is not pinched.

7. Precautions of Use

1. To ensure trouble-free operation, Sartorius Stedim Biotech Flexsafe® 3D Bag for Drum must be used with a dedicated drum whose size must fit. Bag sizes matches drum sizes as described in the container dimensions parts. (see 2. Plastic drum description and dimensions)

2. The drum must be clean and dry before inserting the Flexsafe® 3D Bag for Drum (Refer to the drum cleaning instructions that are delivered with it). Traces of cleaning agents left on the container can potentially damage the Flexsafe® 3D Bag for Drum.

3. It is under the user's responsibility to verify the compatibility of the Flexsafe® 3D Bag for Drum materials with the solutions used in your process. Sartorius Stedim Biotech can provide guidelines for chemical compatibility, biocompatibility and extractables.

4. Avoid the use of sharp objects (scissors, cutters, scalpels, etc.) in the vicinity of the Flexsafe® 3D Bag.

5. Avoid folding the Flexsafe® 3D Bag for Drum other than the original folds.

6. When positioning the Flexsafe® 3D Bag for Drum in the drum and during any adjustment after the initial fill, handle the bag with care and use appropriate force. Avoid pulling with your full strength. If such is required, it is likely inappropriate to adjust the bag at this time due to the fill volume.

7. The Flexsafe® 3D Bag for Drum is for single-use and should not be re-used.

8. Flexsafe® 3D Bag for Drum Storage Conditions

Flexsafe® 3D Bag for Drum can be stored in their original primary packaging at room temperature (5°C to 40°), in a dry environment.

9. Shelf Life of a Flexsafe® 3D Bag for Drum

The shelf life after gamma sterilization has been validated as indicated on the labelling (product packaging and case) and in the specifications. Details are available from Sartorius Stedim Biotech upon request.

10. Product Complaint

When is a complaint justified?
When a deficiency related to the safety, quality, identity or purity or a deficiency in providing a service is identified on a marketed product.

To whom should the complaint be sent?
To your Sartorius Stedim Biotech commercial contact or distributor.

How and which information should be conveyed?
A complaint form will be provided by your Sartorius Stedim Biotech commercial contact and should be returned by e-mail, fax or letter with the following information:

– the bag or bag system product part number and lot number

– the description of the issue

– the description of the process in which the issue was detected

– the amount of products affected

– samples (or pictures if no samples are available)

If samples are returned, they must be empty, rinsed and decontaminated (if applicable). They must be returned with the signed the Health and Safety part of the complaint form.

11. Disclaimers

1. Sartorius Stedim Biotech Flexsafe® 3D Bag is for single-use only. Sartorius Stedim Biotech will not endorse any responsibility for re-use of the Flexsafe® 3D Bag.

2. Sartorius Stedim Biotech will not endorse any responsibility if the Drum instructions for use and the Flexsafe® 3D Bag instructions for use as described in this document are not strictly followed and the above-mentioned Precautions of Use applied. Upon request, Sartorius Stedim Biotech Application Specialists can perform training to any interested end users.

3. Sartorius Stedim Biotech is not responsible for any special, incidental or consequential damages resulting from any legal theory, including lost profits, downtime, goodwill, damage to or replacement of equipment or property.

12. Warranty

Sartorius Stedim Biotech warrants that the Flexsafe® 3D Bag for Drum is produced according to specifications. Unless otherwise provided for in agreed upon specifications, the general Sartorius Stedim Biotech specifications will apply.
In the case of a defective bag, please follow the above-mentioned product complaint procedure.

13. Trademark

Flexsafe® is registered trademark of Sartorius Stedim Biotech.

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